Teaching guide

IDENTIFICATION DETAILS

Degree:	Biotechnology
Scope	Biology and Genetics
Faculty/School:	Experimental Sciences
Course:	DRUG DESIGN
Type:	Optional
ECTS credits:	3
Year:	4
Code:	2047
Teaching period:	Seventh semester
Subject:	Applied Biotechnology
Module:	Biotechnological Processes and Products
Teaching type:	Classroom-based
Language:	Spanish
Total number of student study hours:	75

SUBJECT DESCRIPTION

The course has been organized so that the student acquires solid training in all the parameters and processes necessary to approach rational drug design, just as leading pharmaceutical and biotechnology companies in their sector do. Special emphasis is placed on the importance of optimizing and making the most of the information derived from each individual process, integrating it into a dynamic model.

The drug and medical device development process is an indisputable example of the need for coordinated integration of a wide range of scientific, legal, regulatory, commercial, administrative and logistical disciplines to solve basic needs of human populations. Nowadays, many specialists in the biosanitary area demand modifications in the processes and regulatory requirements associated with the development of medical devices. A decreasing efficiency of the system (higher development cost and lower success rate) has been detected, a

clinical trial crisis (increasingly complex) and a very significant increase in the price of drugs in general and in innovators in particular, has been detected. It is necessary to simplify procedures, accelerate and cheapen the general process of developing these products, maintaining or optimizing the quality, efficacy and safety requirements associated with the final product. The continuous evolution of pathologies associated with increased life expectancy and habits in developed countries, as well as the barriers to healthcare implementation to treat "old" diseases in underdeveloped countries, constantly generate new demands and challenges in the health and clinical fields, such as the identification of biomarkers and genomic, personalized and regenerative medicine. Therefore, it is crucial in the training of new scientists to know in depth the current process of developing medical devices, as well as the incipient needs and challenges in this dynamic and complex field of human knowledge. This knowledge will allow the student to develop and provide critical capacity and creativity when it comes to optimizing, implementing and accelerating processes in the development of these products, as well as reducing the high overall failure rate associated with these developments. The rigor, veracity and quality control of the results during these developments are an indispensable constant, which the student must internalize during the development of the subject. This course covers all phases of the medical device development process, from different points of view, including knowledge of therapeutic areas, health needs, identification of therapeutic targets in the context of basic and applied research, the processes of rational drug design and high-performance pharmacological screening (HTS), the preclinical evaluation of the future drug, including pharmacodynamic, pharmacokinetic, toxicological and drug interaction studies, the approach to the design of clinical trials and the intellectual property of inventors and developers. The knowledge acquired by the student will be easily integrated with other contents of the degree, allowing them to deepen, integrate, locate and contextualize practically any concept in the flow of processes associated with the development of drugs and other medical devices. Special emphasis will also be placed on students acquiring comprehensive training beyond the theoretical aspects that allow them to understand the need that society has for this type of process to continue developing in the future. Let him understand that these are complex, lengthy and complicated processes. To acquire critical thinking about the pharmaceutical and biotechnology sector and the relevance that these sectors have in our society.

GOAL

Health systems require new drugs to address unmet medical needs in different therapeutic areas, and pharmaceutical and biotechnology companies strive to bring new drugs to the market through the long and costly process of drug discovery and development. During the different phases, the potential new drug must demonstrate that it meets the efficacy, safety and quality requirements required for its commercialization and use in patients. These increasingly demanding requirements have had a negative impact on R&D productivity in recent years. This fact has made clear the great need for new innovative approaches, as well as greater collaboration between industry and academia.
The objective of this course is to address the basic and methodological principles of the drug discovery and development process, from knowledge of the biological basis of pathology to the identification of a drug candidate and the confirmation of its preclinical efficacy and safety. Relevant aspects of the transition from preclinical to clinical development will also be reviewed and scientific and operational issues of the entire process, its productivity and possible improvements in its efficiency will be discussed.
It is recommended for those students interested in developing their professional careers in the pharmaceutical and biotechnology sector, both inside and outside the field of R&D.

The specific aims of the subject are:

Know the basic procedures for validating therapeutic targets.

Learn about the different strategies used by the pharmaceutical industry to approach drug design.

Understand the phases of the drug discovery process: times, costs and critical tests at each stage of the funnel.

Know and know how to apply the technologies used in the different drug discovery processes.

Learn how to optimize the tests carried out throughout the drug discovery process: sensitivity, precision, robustness, stability, etc.

Learn how to improve and accelerate drug discovery procedures.

Learn about the most relevant products in drug development in recent history.

Develop habits of rigorous thinking that allow them to always analyze the contents learned with a critical spirit.

PRIOR KNOWLEDGE

It is not necessary for the student to have previous knowledge in the area of the development of drugs and medical devices, since the course aims to take a comprehensive tour with sufficient material to generate a complete understanding from the basics of all processes.
The student taking the subject must have a good level of knowledge of chemistry, biology, biochemistry, pharmacology and experimentation techniques. A good ability to analyze and understand technical and scientific texts in English is highly recommended.

COURSE SYLLABUS

- Introduction to the discovery and development of innovative drugs
- Identification and validation of therapeutic targets
- 'Rational' drug design
- Development and validation of high performance screening (HTS) tests
- Identification of active compounds (Hits)
- Optimization of active compounds (Hit to Lead process)
- Preclinical drug development, pharmacokinetics, pharmacodynamics, toxicity, drug interaction
- Clinical drug development
- Analysis of a case study

EDUCATION ACTIVITIES

FACE-TO-FACE ACTIVITIES
- Participatory expository classes: Master classes in which the contents of the program are developed. The slides used for class presentations will be available online through the course platform. Student participation will be encouraged and valued in the form of technical or scientific discussions raised by the teacher or the students

themselves.
- Seminar. Seminar focused on providing students with the basic knowledge to prepare and present a project for the discovery and development of an innovative drug, or alternatively the study and analysis of a scientific work related to the subject matter. As part of this training activity, the oral presentation of these projects will be included in the classroom. The work will be carried out individually or in teams, depending on the number of students enrolled and the availability of schedules (students will be notified well in advance).
- Tutoring (optional). Personalized or small group tutoring for the resolution of doubts and pedagogical support.
- Exam to evaluate theoretical knowledge.
NON-FACE-TO-FACE ACTIVITIES
- Autonomous study: theoretical study and preparation of face-to-face activities. - Virtual network work.

DISTRIBUTION OF WORK TIME

TEACHER-LED TRAINING ACTIVITIES	INDIVIDUAL WORK
30 Horas	45 Horas

SKILLS

Basic Skills

Students must have demonstrated knowledge and understanding in an area of study that is founded on general secondary education. Moreover, the area of study is typically at a level that includes certain aspects implying knowledge at the forefront of its field of study, albeit supported by advanced textbooks

Students must be able to apply their knowledge to their work or vocation in a professional manner and possess skills that can typically be demonstrated by coming up with and sustaining arguments and solving problems within their field of study.

Students must have the ability to gather and interpret relevant data (usually within their field of study) in order to make judgments that include reflections on pertinent social, scientific or ethical issues

Students must be able to convey information, ideas, problems and solutions to both an expert and non-expert audience

Students must have developed the learning skills needed to undertake further study with a high degree of independence

Capacity for teamwork and group management.

To have acquired the ability for analytical, synthetic, reflective, critical, theoretical and practical thought.

Capacity for problem-solving and decision-making.

To develop capacity for and a commitment to learning and personal development.

To develop an ability to search for, take in, analyze, sum up and relate information.

To develop oral and written communication skills.

General Skills

Capacity for teamwork and group management.

To have acquired the ability for analytical, synthetic, reflective, critical, theoretical and practical thought.

Capacity for problem-solving and decision-making.

To develop capacity for and a commitment to learning and personal development.

To develop an ability to search for, take in, analyze, sum up and relate information.

To develop oral and written communication skills.

Specific skills

Describe the most relevant biotechnological products in the development of new drugs (vaccines, monoclonal antibodies, chemokines and cytokines, peptides and proteins, antisense oligonucleotides and interfering RNA).

Point out the influence and contributions of new technologies in Molecular and Cellular Biology to the pharmaceutical sector.

Develop habits of rigorous thinking

Ability to communicate the knowledge acquired orally and in writing.

Know how to apply the theoretical knowledge acquired to solving problems and practical cases related to different subjects.

Analyze and synthesize the main ideas and contents of all types of texts; discover the theses contained in them and the issues they raise, and critically judge their form and content.

Develop criteria for problem solving and decision-making both in the professional and personal spheres.

Cultivate an attitude of intellectual concern and the search for truth in all areas of life.

LEARNING RESULTS

Explain the importance of properly validating targets of therapeutic interest.

Understand the advantages and disadvantages of the two fundamental approaches to drug discovery and know how to choose the most appropriate one for each situation.

Describe the most relevant products in the development of new drugs (NME) in recent history (biotechnological versus small molecules).

Differentiate the mechanisms of action of different drugs (Reversible vs Irreversible; competitive vs non-competitive or acompetitive; agonists vs antagonists; allosteric modulators, etc.) .

Know how to optimize an assay: sensitivity, selectivity, robusted, controls, references, etc.||Design the optimization of a mass screening process (HTS) including predictive analysis and SAR methods.

Describe the fundamental strategies in the discovery of new drugs throughout history: targeted versus functional approaches.

Learn about the different biochemical, cellular and animal models currently used in the pharmaceutical sector and that allow us to determine the potency of new drugs both in vitro and in vivo.

Learn about the cutting-edge tools and technologies that make it possible to develop homogeneous and highly sensitive tests that are easy to automate.

Interpret the influence of selectivity and residence time on drug toxicity.

Describe the key aspects of drug development to improve their pharmacokinetic and pharmacodynamic behavior.

Describe the fundamental targets against which new drugs are directed (Enzymes, receptors, ion channels, others) .

Identify the contributions of new technologies and analysis tools to the pharmaceutical sector.

LEARNING APPRAISAL SYSTEM

Ordinary system:

(E1) FINAL EXAM (Individual): 70% of the final grade of the subject.
(E2) PROJECT or expository work on scientific publication (individual/groups): 20% of the final grade of the subject. The project will assess the content, the revised bibliography and level of development of each part of the project, as well as the clarity and organization of the oral presentation, the design and clarity of the slides, and the ability to respond to the questions posed by the listeners (students and teacher). It will be the teacher's discretion to evaluate the personal contribution to the work if the exercise is carried out by more than one student.
(E3) Attendance and participation in face-to-face classroom activities: 10% of the final grade of the subject
Additional information about the evaluation

The final grade of the subject will be calculated using the formula: 70% E1 + 20% E2 + 10% E3.
It will be necessary to obtain a minimum grade of 5 in the sections (E1 and E2) to complete the weighted sum of all the parts of the subject (E1, E2 and E3). In the event that the Ordinary Call obtains a score of < 5 in E2, a new

work must be submitted in the Extraordinary Call. If a grade equal to or greater than 5 were obtained in E2, and the minimum grade required for E1 was not obtained, the result of E2 would be saved for the extraordinary call (there would be no need to repeat the work). In the same way, if E1 were to obtain a grade equal to or greater than 5 and this requirement for E2 were not exceeded, the student would have to apply for E2 in the extraordinary call, in which case, the oral presentation of the work would be made only to the teacher, after having already finished the classes (Both E1, E2 and E3 are saved for the extraordinary call).
Alternative evaluation system:
Students in second enrollment and in a situation of academic exemption will be evaluated with the same criteria described above, with the same percentages for the qualification of each of the components of the evaluation described above. Students in second or subsequent enrollment must contact the teacher to request to take advantage of this system.
Plagiarism, as well as the use of illegitimate means in evaluation tests, will be sanctioned in accordance with those established in the Evaluation Regulations and the University's Coexistence Regulations.

ETHICAL AND RESPONSIBLE USE OF ARTIFICIAL INTELLIGENCE

1.- The use of any Artificial Intelligence (AI) system or service shall be determined by the lecturer, and may only be used in the manner and under the conditions indicated by them. In all cases, its use must comply with the following principles:
a) The use of AI systems or services must be accompanied by critical reflection on the part of the student regarding their impact and/or limitations in the development of the assigned task or project.
b) The selection of AI systems or services must be justified, explaining their advantages over other tools or methods of obtaining information. The chosen model and the version of AI used must be described in as much detail as possible.
c) The student must appropriately cite the use of AI systems or services, specifying the parts of the work where they were used and describing the creative process followed. The use of citation formats and usage examples may be consulted on the Library website(https://www.ufv.es/gestion-de-la-informacion_biblioteca/).
d) The results obtained through AI systems or services must always be verified. As the author, the student is responsible for their work and for the legitimacy of the sources used.
2.- In all cases, the use of AI systems or services must always respect the principles of responsible and ethical use upheld by the university, as outlined in the Guide for the Responsible Use of Artificial Intelligence in Studies at UFV. Additionally, the lecturer may request other types of individual commitments from the student when deemed necessary.
3.- Without prejudice to the above, in cases of doubt regarding the ethical and responsible use of any AI system or service, the lecturer may require an oral presentation of any assignment or partial submission. This oral evaluation shall take precedence over any other form of assessment outlined in the Teaching Guide. In this oral defense, the student must demonstrate knowledge of the subject, justify their decisions, and explain the development of their work.

BIBLIOGRAPHY AND OTHER RESOURCES

Basic

Chris Rostron. Drug design and development/Oxford: Oxford University Press, 2020.

edited by David B. Weiner and William B, Williams. Chemical and structural approaches to rational drug design/

edited by Oliver Kayser, Rainer H. Müller. Pharmaceutical BiotechnologyDrug Discovery and Clinical Applications/Germany:Wiley-VCH Verlag GmbH & Co. KGaa,2005.

[edited by] Zoran Rankovic, Richard Morphy. Lead generation approaches in drug discovery [electronic

resource]/Hoboken, NJ:Wiley, c2010.

[edited by] Shayne Cox Gad. Preclinical development handbook.Toxicology [electronic resource]/Hoboken, NJ:Wiley-Interscience, c2008.

[edited by] Shayne Cox Gad. Preclinical development handbook.ADME and biopharmaceutical properties [electronic resource]/Hoboken, N.J.:Wiley-Interscience, c2008.

edited by Mitchell N. Cayen. Early drug development [electronic resource]:] strategies and routes to first-in-human trials/Hoboken, N.J.:Wiley, c2010.

edited by J. Suso Platero. Molecular pathology in drug discovery and development [electronic resource]/Hoboken, N.J.:John Wiley, c2009.

edited by Konstantin V. Balakin. Pharmaceutical data mining [electronic resource]:] approaches and applications for drug discovery/Hoboken, NJ:Wiley, c2010.

edited by Vishal S. Vaidya, Joseph V. Bonventre. Biomarkers [electronic resource]:] in medicine, drug discovery, and environmental health/Hoboken, N.J.:Wiley, c2010.
(edited by Vishal S. Vaidya, Joseph V. Bonventre. Biomarkers [electronic resource]:] in medicine, drug discovery, and environmental health/Hoboken, N.J.:Wiley, c2010. , ||William S. Kisaalita. 3D cell-based biosensors in drug discovery programs [electronic resource]:] microtissue engineering for high throughput screening/Boca Raton, [FL] :CRC Press, 2010.)

edited by Albert P. Li. Drug-drug interactions in pharmaceutical development [electronic resource]/Hoboken, n.j.:Wiley-Interscience, c2008.

edited by Annpey Pong, Shein-Chung Chow. Handbook of adaptive designs in pharmaceutical and clinical development [electronic resource]/Boca Raton:CRC Press,2011.

edited by Chao Han, Charles B. Davis, Binghe Wang. Evaluation of drug candidates for preclinical development [electronic resource]:] pharmacokinetics, metabolism, pharmaceutics, and toxicology/Hoboken, NJ:John Wiley & Sons, c2010.

edited by Leon Shargel, Isadore Kanfer. Generic drug product development [electronic resource]:] specialty dosage forms/New York:Informa Healthcare USA, c2010.